AUBURN
School of Kinesiology

Digitally-Delivered Intervention to Prompt Physical Activity

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INFORMED CONSENT DOCUMENT

(NOTE: DO NOT SIGN THIS DOCUMENT UNLESS AN IRB APPROVAL STAMP WITH CURRENT DATES HAS BEEN APPLIED TO THIS DOCUMENT.)

Title of research study: *Digitally-Delivered Intervention to Prompt Physical Activity*
Investigator: *Dr. C.J. Brush*

KEY INFORMATION

The following table is a short summary of this study to help you decide whether or not you would like to participate in this research study. More detailed information is listed later on in this form.

General Information	Depression is a prevalent mental health condition globally; however, access to proper mental health services is inadequate in the United States and across the globe. Digital interventions offer a potential solution to increase ease of access by using technology—such as smartphones and mobile apps—and change health behaviors, such as physical activity. However, many require continued access to guidance and supervision from mental health providers during intervention delivery, resulting in an unmet need for scalable, self-guided alternatives. This study aims to test the effects of a digital intervention on physical activity levels and whether changes in physical activity levels relate to changes in depressive symptoms in adults experiencing clinical symptoms of depression. Participation will involve the completion of questionnaires, two lab visits separated by a week of physical activity monitoring, four weeks of an at-home digital physical activity intervention or control, and another two lab visits separated by a week of at-home physical activity monitoring. At the lab visits, there will also be a recording of brain activity using electroencephalography (EEG).
Purpose	This research aims to better understand whether a digitally delivered intervention can change physical activity levels, and whether there is a relationship with mental health outcomes.
Duration & Visits	All study procedures will take 6 weeks to complete including a 4-week intervention period. Before and after the intervention period, there will be 2 in-person laboratory visits. These visits will last approximately 1-1.5 hours each.
Overview of Procedures	If you decide that you want to participate in this study and are eligible, you will be asked to complete the following: ○ Pre-Intervention: You will be asked to attend 2 laboratory visits to collect pre-intervention measures in the following order. ○ First lab visit (~1 hour): ■ Questionnaires ■ Physical activity monitoring ○ Second lab visit (~1.5 hour): ■ Questionnaires ■ EEG recording and computerized tasks

	■ Intervention assignment ○ Intervention period (4 weeks): ■ Digital intervention ■ Control condition ■ Questionnaires ○ Post-Intervention: ○ Third lab visit (~1.5 hour): ■ Questionnaires ■ EEG assessment and computerized tasks ■ Physical activity monitoring ○ Fourth lab visit (~1 hour): ■ Semi-structured interview (Digital intervention group only)
Risks	There are some risks involved by participating in all research studies; however, this study may involve minimal risks. You may experience mental fatigue or mild psychological distress or discomfort in response to the task performed during the EEG recordings or questions asked about your mood or anxiety or depressive symptoms. It is possible to experience temporary and mild skin irritation (redness) where the electrode sensor meets your scalp during the EEG portions of the study. If you perform physical activity, you may experience increased heart rate and respiration rate, and muscular fatigue. There are no funds available for compensation for study-related injuries.
Benefits	Although there is no direct or intended benefit for participating in this study, you may help others in the future by advancing the scientific understanding of whether technology can be used to benefit physical health and mental health.
Alternatives	The alternative is not to participate in this study.
Right to Withdraw from the Study	Your decision to be in this study is voluntary. If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.

DETAILED INFORMATION

The following is more detailed information about this study.

Why am I being invited to take part in a research study?

You are invited to participate in a research study that aims to better understand whether a digitally delivered intervention can change physical activity levels, and whether there is a relationship with mental health outcomes. The study is being conducted by Dr. C.J. Brush, Principal Investigator, and Karly Knudson, Graduate Student Researcher, in the Auburn University School of Kinesiology. You were selected as a possible participant because you are 19 years of age or above, are able to engage in physical activity, are experiencing current depressive symptoms, have an Apple or Android mobile device, are willing to download the Pathverse mobile app on your Apple or Android mobile device to answer questions at home, are willing to keep your Apple or Android mobile device powered on to receive and respond to notifications from the Pathverse mobile app between visits, and can help us learn about how the digital promotion of physical activity may alleviate symptoms of depression.

How many people will be studied?
We expect about 50 people locally will participate in this research study.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part in the research study is up to you. You may wish to talk to your family and friends about participating in the study.
- You can choose not to take part in the study.
- You can agree to take part in the study and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide whether you would like to take part in the study or not.

Why is this research being done?
Depression is a prevalent mental health condition. Following the COVID-19 pandemic, not only has the prevalence of mental health conditions increased, but mental health services have also become more challenging to access. There is an urgent need to understand the effectiveness of alternative, scalable and accessible strategies that can be used in the prevention, treatment, and management of depression.

What will be involved if I participate?
If you decide to participate in this research study, you will be asked to complete a battery of questionnaires, two lab visits separated by a week of physical activity monitoring, four weeks of an at-home physical activity intervention or control, and another two lab visits separated by a week of at-home physical activity monitoring. At the lab visits, there will also be a recording of brain activity using electroencephalography (EEG). All study procedures will take 6 weeks to complete. Specifically, as a research participant, you will be asked to complete the following:

- Pre-Intervention: You will be asked to attend two laboratory visits to collect pre-intervention measures in the following order.
  - First lab visit (~1 hour):
    - You will complete questionnaires and have your height and weight measured.
    - After completing the above procedures and before leaving the laboratory, you will be instructed to wear a physical activity monitor device on your non-dominant wrist for about seven days and indicate when you wear the watch.

  - Second lab visit (~1.5 hours):
    - After the seven-day period, you will return to the lab and return the accelerometer.
    - Your brain activity will then be recorded using EEG during computerized tasks (see “Information about the Computerized Tasks” for more task details). To do this, we will use a special cap that contains up to 32 electrode sensors that you wear on your head. To record brain activity, the sensors need a small amount of gel to help accurately record brain activity at the scalp. The EEG recording is completely painless, non-invasive, and safe. It is like heart rate recordings taken during routine physical exams.
    - Since your hair and/or facial skin may have some gel from the electrode sensors from the brain recordings, you will have the opportunity to wash the gel off using one of the showers in the locker rooms located next to the

Psychophysiology of Active Lifestyles Laboratory. Research staff will provide you with a towel and shampoo/conditioner at any time should you want to use the shower facilities to wash the gel off.
        - At this time, you will learn details of the condition that you are randomly assigned to complete for the next four weeks at home (i.e., outside the lab).
- Intervention/Control:
    - Digital intervention (4 weeks):
        - You will be instructed to download the Pathverse mobile app on your Apple or Android device. The Pathverse platform will be used to send participants daily notifications regarding physical activity. This platform uses anonymous data collection and does not collect any personally identifiable information (PII). The app will also not collect any GPS location data in anonymous data collection mode. You will download the Pathverse mobile app and will use your study ID number provided by the research team to link out-of-lab responses to the data collected in the lab. No other identifying information is collected. All data collected is encrypted and is behind a password-protected account that will only be accessed by the research team. During onboarding, you will choose five forms of physical activity you would like to engage in over the four-week intervention. You will be instructed on how to report the physical activity they engaged in, as well as its duration and intensity. You will have the choice of at what time you would like to receive notifications each day.
    - Control Condition (4 weeks):
        - In this condition, we will track your natural course of depression over four weeks. After the four-week intervention and completion of post-intervention visits, you will be offered the above intervention, if you would like.
    - Two weeks into the intervention and control procedures, you will be sent an email to complete a brief questionnaire about your mood and mental health.
- Post-Intervention:
    - Third lab visit (~1.5 hours):
        - After the four weeks, you will return to the lab and be instructed to delete the Pathverse app platform after research staff has downloaded participant data and will complete the same procedures as pre-intervention. This includes completing questionnaires, an EEG assessment, and receiving an accelerometer to be worn for another seven-day period.
    - Fourth lab visit (~1 hour):
        - After the approximate seven-day period between visits, you will return to the lab and return the accelerometer. At this time, if you completed the digital intervention, you will participate in a semi-structured qualitative interview and complete questionnaires to gather feedback for potential refinements to the intervention. Interviews will be recorded and transcribed. You will have the opportunity to review your interview transcripts. After these procedures are complete, payment will be distributed, and the study will be complete.

Information about the Computerized Tasks

Resting Task (~5 min): You will complete a recording of your brain activity while wearing the EEG electrode cap for 5 min while sitting comfortably in a chair while your eyes are either open or closed over the task.

Effort Doors Task (~20 min): During each trial you will first be presented with an image of a locked padlock on the screen. Above the lock you'll see a number which indicates the number of times you are to press the "p" or "q" keys with your nondominant pinky finger to unlock the padlock. Once unlocked, an image of two doors will appear for you to choose from. Your choice will be followed by a green arrow with visual stimuli that differ as a function of winning or losing money or breaking even. On each trial, you can either win, lose, or break even depending on your performance on the task. Because of that, you will have the opportunity to win bonuses up to $15, with a potential win of 50 cents on each trial, loss of 25 cents on each trial, or break even. This task takes approximately 20 minutes to complete.

After all procedures are complete, you will receive payment for your participation (see "*Will I receive compensation for participating?*" for more details). All procedures completed during laboratory visits will be carried out by trained members of the research staff in room 148 of the Kinesiology Building at Auburn University.

The intervention you get will be chosen by chance, like flipping a coin. Neither you nor the research personnel will choose what treatment you will receive. You will have an equal chance of being assigned to the digital intervention or control group.

If you are assigned to the digital intervention group, you will be asked to participate in a semi-structured qualitative interview and complete questionnaires to gather feedback for potential refinements to the intervention. Interviews will be recorded and transcribed. You will have the opportunity to review your interview transcripts. Interviews will be audio recorded to ensure that participant responses are accurately transcribed. You have the right to refuse the audio recording after reviewing the audio consent form.

How long will the research last and what will I need to do?

All study procedures will take approximately 6 weeks to complete, during which you will be asked to attend 4 laboratory visits lasting approximately 1.5 hours each and participate in a 4-week intervention period.

Is there any way being in this study could be bad for me?

There are some risks involved by participating in all research studies; however, this study may involve minimal risks. You may experience mental fatigue or mild psychological distress or discomfort in response to the task performed during the EEG recordings or questions asked about your mood or anxiety or depressive symptoms. It is possible to experience temporary and mild skin irritation (redness) where the electrode sensor meets your scalp during the EEG portions of the study. If you perform physical activity, you may experience increased heart rate and respiration rate, and muscular fatigue. There are no funds available for compensation for study-related injuries.

This study involves in-person research activities that carry an inherent risk for transmission of illnesses including respiratory viruses such as COVID-19, flu, and RSV. Should you feel uncomfortable, you can either ask researchers to wear a mask or elect not to participate in this research project.

We will do our best to protect your data and samples during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that people who are not supposed to might access your data and samples. In either case, we cannot reduce the risk to zero.

Auburn University will not provide any payment if you are harmed as a result of participating in this study. You are responsible for medical costs incurred as a result of participation in this study.

To minimize these risks, you will have the opportunity to ask questions about any of the study procedures and are free to terminate participation at any point in time throughout the study.

If you experience mild discomfort and/or fatigue during parts of the self-reported or EEG assessments, you can take a break, skip, or terminate your participation on those parts if you choose. Further, if you experience discomfort during the EEG recordings due to the electrode gel, you are free to terminate that procedure at any time.

While wearing the physical activity monitor device, if you experience discomfort or skin irritation, you can remove the device at any time or discontinue that data collection portion of the study.

Will being in this study help me in any way?

Although there is no direct or intended benefit from being in this study, you may help others in the future by advancing the scientific understanding of whether technology can be used to benefit physical health and mental health.

Will I receive compensation for participating?

You have the option to receive either SONA credit or monetary compensation for participation.

For those interested in receiving SONA credit for participation:

You will earn 1 SONA credit for each of the laboratory visits (4 total) you attend. This total of 4 credits will be provided at the end of study participation. If you choose to withdrawal from the study, you will be compensated appropriately for the time you participated.

For those interested in receiving monetary compensation for compensation:

You have the opportunity to earn up to $60 ($10 for each week of participation) in the form of cash for participation in the study. If you choose to withdrawal from the study, you will be compensated appropriately for the amount of time you participated.

Payment will be distributed as outlined below.

- At the end of the second in-person laboratory visit, you will receive $10
    - At the end of your third in-person laboratory visit, you will receive $40
    - At the time of your fourth and final in-person laboratory visit you will receive $10

Bonus monetary compensation for task performance:

Regardless of your preferred method of compensation, you will have the opportunity to earn up to $30 total as additional compensation depending on your performance during the computerized reward tasks that will take place during visit 2 (up to $15) and visit 3 (up to $15).

Note, if the physical activity monitor is lost or damaged beyond repair, you will not be given compensation for the remaining procedures to allow the research team to recover the costs associated with damaged equipment. At the time of each payment, you will be asked to sign a compensation receipt with your legal name and the date acknowledging that you received compensation. Receipts will be stored separately from study data in a locked file cabinet in Dr. Brush's office for up to one year following the completion of the study.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision not to participate or to stop participating will not jeopardize your future relations with Auburn University or the School of Kinesiology. Your alternative to participating in this research study is to not participate.

What are my responsibilities if I take part in this research?
Participants will be responsible for arriving at the study visits, which may include your own cost of transportation (e.g., gasoline, parking).

What happens if I say yes, but I change my mind later?
Your participation in this research study is completely voluntary. You may choose not to be a part of this study. There will be no penalty to you if you choose not to take part. At any time, you may choose not to answer specific questions or may stop participating at any time. You will be given a copy of the consent form for your records.

If you withdraw from the study, all data collected up to that point will be retained and no new data will be collected.

You can leave the research at any time; it will not be held against you. If you choose to withdraw, your data can be withdrawn as long as it is identifiable.

What happens to the information collected for the research?

Your privacy will be protected. All information gathered in this study will be kept as confidential as possible and to the extent allowed by federal and state laws. Under certain circumstances, information that identifies you may be released for internal and external reviews of this project.

All study data will be kept separate from your identifiable information by use of study ID numbers. This includes any data collected using the Pathverse mobile app platform. Participants will be provided with an e-mail address by the research team, which will be linked only to your study ID number provided by the investigative team. The link between your contact information and your study ID number will be kept in a password-protected file only accessible by the investigative team. Any paper materials will be stored in a locked room in the laboratory and electronically collected data will be stored on a computer with restricted access through password protection accessible only by the investigative team. Interview participants will select a pseudonym, and all data obtained will be attached to your pseudonym with no personal identification presented or attached to the participants' names.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Additionally, information collected during this study may be used for future research studies or distributed to other researchers for future research without your additional permission. Any identifiers will be removed so that the information or samples are anonymous and cannot be linked back to you. The anonymous data and/or results of this study may also be published or presented at professional meetings, but the identities of any participant will remain anonymous. We also plan to keep your data for a minimum of five years. If you do not agree with any of the above, you may choose not to join the study.

FUTURE USE OF DATA

If identifiers are removed from your identifiable private information or identifiable data that are collected during this research, that information or those data could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your research records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

This study is collecting data from you. We would like to make your data available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Your data may be shared with researchers around the world. Our goal is to make more research possible. We plan to keep your data and samples for 5 years after the study ends. To get your data, future researchers must seek approval from this institution and review by an IRB may be required.

We will protect the confidentiality of your information to the extent possible. Your data will be coded to protect your identity before it is shared with other researchers. Only the research staff will have the password to access electronic records, and the locked file cabinets storing hard copies that can be used to link to your identifying information.

Participating in this study means you agree to share your data. You can change your mind later, but researchers might still use your data if it has already been shared. If you do not want your data used for other research studies, you should not participate in this study.

What else do I need to know?

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. Auburn University has no program to pay for medical care for research-related injuries.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you can contact the primary investigator, Dr. C.J. Brush, by email at cjbrush@auburn.edu or the project coordinator, Karly Knudson, at kak0146@auburn.edu.

This research has been reviewed and approved by the Auburn University Institutional Review Board (IRB). You may contact the Auburn University IRB at (334) 844-5966 or IRBadmin@auburn.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Having read the information provided, you must decide whether or not you wish to participate in this research study. Your signature documents your permission to take part in this research. A copy of this document will be given to you to keep.

Signature of subject	Date
Printed name of subject	Date
Signature of person obtaining consent	Date
Printed name of person obtaining consent	